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KRSEK STAPLES,J	
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This is a communication from the examiner in charge of your application.
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for restriction purposes only

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire one month(s), ——— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-121 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-121 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-12 and 61, drawn to a nucleic acid sequence coding for *Cry j* I, a host cell and expression vector classified in Class 435, subclass 69.3.

II. Claims 13, 41, 47-49, 106, and 107, drawn to purified *Cry j* I, classified in Class 530, subclass 370.

III. Claims 14-19, drawn to a nucleic acid sequence coding for *Jun s* I, a host cell and expression vector classified in Class 435, subclass 69.3.

IV. Claims 20, 70, 71, 73, and 74 drawn to isolated *Jun s* I, classified in Class 530, subclass 370.

V. Claims 21-26, drawn to a nucleic acid sequence coding for *Jun v* I, a host cell and expression vector classified in Class 435, subclass 69.3.

VI. Claims 27, 70, 71, 72, 77 and 78 drawn to isolated *Jun v* I, classified in Class 530, subclass 370.

VII. Claim 28, drawn to a method of producing *Jun s* I, classified in Class 435, subclass 69.3.

VIII. Claim 29, drawn to a method of producing *Jun v* I, classified in Class 530, subclass 370.

IX. Claims 30-38, and 95, drawn to a nucleic acid sequence coding for *Cry j* II, a host cell and expression vector classified in Class 435, subclass 69.3.

X. Claims 39, 81-84, 108, 109, and 120, drawn to isolated *Cry j* II, classified in Class 530, subclass 370.

XI. Claim 40, drawn to a method of producing *Cry j* II, classified in Class 530, subclass 370.

XII. Claims 42-46, 50, 54, 56, 57, 58, 59, 60, 62-64, 66, 69, 102, 110-112, and 118, drawn to a fragment of *Cry j* I and a modified peptide, classified in Class 530, subclass 324.

XIII. Claims 51, 67, 68, 103 and 104 drawn to a method of treating sensitivity to Japanese cedar pollen allergen using *Cry j* I, classified in Class 424, subclass 275.1.

XIV. Claims 52 and 119, drawn to a method of detecting sensitivity to Japanese cedar pollen using *Cry j* I, classified in Class 436, subclass 501.

XV. Claim 53, drawn to a monoclonal antibody to *Cry j* I, classified in Class 530, subclass 388.5

XVI. Claim 55, drawn to a method of designing antigenic fragments of *Cry j* I, classified in Class 435, subclass 68.1.

XVII. Claim 65, drawn to a peptide containing at least two T cell epitopes of *Cry j* I, classified in class 530, subclass 324.

XVIII. Claims 75 and 79, drawn to a method of treating sensitivity to Japanese cedar pollen allergen using *Jun s* I, classified in Class 424, subclass 275.1.

XIX. Claim 76, drawn to a method of detecting sensitivity to Japanese cedar pollen using *Jun s* I, classified in Class 436, subclass 501.

XX. Claim 80, drawn to a method of detecting sensitivity to Japanese cedar pollen using *Jun v* I, classified in Class 436, subclass 501.

XXI. Claims 85-91, 96-98, and 113, drawn to a fragment of *Cry j* II and a modified peptide, classified in Class 530, subclass 324.

XXII. Claims 92, 99, and 101, drawn to method of treating sensitivity to Japanese cedar pollen allergen using *Cry j* II, classified in Class 424, subclass 275.1.

XXIII. Claims 93 and 121, drawn to a method of detecting sensitivity to Japanese cedar pollen using *Cry j* II, classified in Class 436, subclass 501.

XXIV. Claim 94, drawn to a monoclonal antibody to *Cry j* II, classified in Class 530, subclass 388.5.

XXV. Claims 100, 105, 114, 115, 116, and 117 drawn to a therapeutic composition and method of treating sensitivity to Japanese cedar pollen using a mixture of *Cry j* I and *Cry j* II, classified in Class 424, subclass 275.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, XII and XIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Cry j* I protein or peptide of Groups II and XII can be used in a method of detecting sensitivity to Japanese cedar pollen.

Inventions IV and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Jun s* I protein of group IV can be used in a method of detecting sensitivity to Japanese cedar pollen.

Inventions VI and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Jun v* I protein of group VI can be used in a method of treating sensitivity to Japanese cedar pollen.

Inventions X, XXI and XXII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Cry j* II protein or peptide of Groups X and XXI can be used in a method of detecting sensitivity to Japanese cedar pollen.

Inventions II, XII and XIV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Cry j* I protein or peptide of Groups II and XII can be used in a method of treating sensitivity to Japanese cedar pollen.

Inventions IV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Jun s* I protein of group IV can be used in a method of treating sensitivity to Japanese cedar pollen.

Inventions X, XXI and XXIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the *Cry j* II protein or peptide of Groups X and XXI can be used in a method of treating sensitivity to Japanese cedar pollen.

Inventions I, III, V, and IX are drawn to four structurally distinct nucleic acid sequences which encode four different proteins which are also structurally and functionally distinct.

Inventions II, IV, VI, X, XII, XVII, and XXI are drawn to four different proteins and multiple peptides each having different amino acid sequences, biological activities and biochemical properties.

Inventions XV and XXIV are drawn to two monoclonal antibodies which have different binding properties and recognize different proteins.

The nucleic acids of Inventions I, III, V, and IX, the proteins and peptides of Inventions II, IV, VI, X, XII, XVII and XXI, and the monoclonal antibodies of Inventions XV and XXIV are materially different compositions having different structures, biological activities, and biochemical properties.

Inventions VII, VIII and XI are drawn to methods for the purification of three structurally and functionally distinct proteins. Because these proteins have different molecular weights and

biochemical characteristics, the methods of purifying these proteins would not involve the same method steps.

Inventions XIII, XVIII, XXII and XXV are drawn to methods of treating sensitivity to Japanese cedar pollen. Each of these methods involves materially different method steps in that each method involves the administration of a protein which is structurally and functionally distinct from the proteins of the other groups.

Inventions XIV, XIX, XX and XXIII are drawn to methods of detecting sensitivity to Japanese cedar pollen. Each or these methods involves materially different method steps in that each method involves as assay using a protein which is structurally and functionally distinct from the proteins of the other groups.

The methods of treating sensitivity to Japanese cedar pollen of Inventions XIII, XVIII, XXII and XXV, the methods of detecting sensitivity to Japanese cedar pollen of Inventions XIV, XIX, XX and XXIII, the methods for the purification of proteins of Inventions VII, VII and XI, and the method of designing antigenic fragments of Invention XVI are all materially different methods which require different method steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If Inventions I, XII, XIII, XVII, XXI, or XXV are elected then these inventions are subject of the following Species Election. Due to the large number of peptides which are considered separate species in this Application, each peptide is not listed separately below, but rather the claim in which the peptides appear are listed below.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention I:

Claim 61 of Invention I is drawn to an isolated nucleic acid sequence encoding a peptide of claim 56. The species are listed as amino acid sequences having individual sequence I.D numbers in claim 56.

Invention XII:

Claim 54 of Invention XII is drawn to an isolated peptide of *Cry j* I. Five species are listed as amino acid residues 1-40 or 81-110 or 151-180 or 191-240 or 291-330 of SEQ ID NO 2.

Claim 56 of Invention XII lists multiple species of peptides as amino acid sequences having individual sequence I.D. numbers.

Claims 69 and 112 of Invention XII lists 14 species of peptides having SEQ ID Nos 119-132.

Claim 102 of Invention XII lists 4 species of peptides having SEQ ID nos 119, 128, 129, and 132.

Invention XIII:

Claim 104 of Invention XIII lists lists 14 species of peptides having SEQ ID Nos 119-132.

Invention XVII:

Claim 65 of Invention XVII lists multiple species of peptides as amino acid sequences having individual sequence I.D. numbers.

Invention XXI:

Claim 96 of Invention XXI lists six separate species of peptides having SEQ ID Nos 187-192.

Invention XXV:

Claim 115 of Invention XXV lists multiple species of peptides as amino acid sequences having individual sequence I.D. numbers.

Each of the peptide sequences or nucleic acid sequence which encodes the peptide sequence listed above is considered a patentably distinct species because the peptides each have a unique amino acid sequence and have different functional activities (i.e. T cell and B cell epitopes).

Applicant is required under 35 U.S.C. § 121 to elect a species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie K. Staples whose telephone number is (703) 305-7556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission via the PTO Fax Center, located in Crystal Mall 1. The Fax Center number is (703) 305-7939. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

JKS
Julie K. Staples, Ph.D.
March 27, 1995

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180